

Applicant: Rahal, James
U.S. Serial No.: 09/935,966
Response to Non-Compliant Amendment
Page 5

REMARKS

In responding to the Office Action, Applicant conducted a telephone interview with Examiner Winkler on January 20, 2004. Applicant thanks the Examiner for the time generously extended for this interview. During this interview, the pending rejection and amendments to the claims were discussed. Applicants presented arguments for patentability that the Examiner indicated may render the present application allowable over Crance et al. Travaux 1999 ("Crance") and U.S. Patent No. 6,387,365 ("Albrecht"). These arguments are presented below.

Applicant has amended claim 5, as discussed during the interview, to include methods for preventing or treating meningitis, encephalitis, or meningo-encephalitis caused by West Nile virus infections by administering an effective amount of interferon alpha-2b. Support for this amendment is found in the specification, for example, at page 4, lines 23-28. By this amendment, Applicant has also added claims 17-24, which are directed to methods of treating West Nile virus infections by administering interferon alpha-2b subcutaneously or intravenously to humans. Support for claims 17-24 is found in the specification, for example, at page 4, lines 10-15, and page 8, lines 7-8, and claims 5-9 as originally filed. Applicant submits that no new matter is added by this amendment. Entry of the amendment, and reconsideration of the application as amended is respectfully requested.

Rejection Under 35 U.S.C. § 103(a)

The Examiner rejects claims 5-9 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Crance in view of Albrecht. Applicant respectfully traverses this rejection.

The Examiner asserts that Crance discloses the effect in cell culture of interferon-alpha 2b on different flaviviruses including West Nile. The Examiner concedes that Crance does not disclose administering interferon alpha-2b to a patient. However, the Examiner uses Albrecht for teaching that interferon alpha-2b can be used at doses of 3 to

Applicant: Rahal, James
U.S. Serial No.: 09/935,966
Response to Non-Compliant Amendment
Page 6

10 million IU for treating patients that have chronic hepatitis C viral infections. Although the Examiner concedes that Albrecht does not teach treating West Nile virus infections using interferon alpha-2b, nevertheless, the Examiner concludes that one of ordinary skill in the art would have "a high expectation of success" in using interferon alpha-2b to treat West Nile virus infections in view of Crance's *in vitro* cell culture results and Albrecht's teachings of using interferon to treat hepatitis C infections. (Office Action, Page 4)

Applicant respectfully disagrees with the Examiner's position. To establish a *prima facie* case of obviousness, all of the claim elements must be taught or suggested by the prior art. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir.1991). The claims have been amended to include that the interferon alpha-2b is used to prevent or treat meningitis, encephalitis, or meningo-encephalitis caused by West Nile virus infection.

Although Crance discloses interferon alpha-2b activity on West Nile virus in select cell lines, Crance does not disclose, teach or suggest using interferon alpha-2b for the prevention or treatment meningitis, encephalitis, or meningo-encephalitis caused by West Nile virus infections. Applicant respectfully submits that West Nile virus meningitis, encephalitis, or meningo-encephalitis is a central nervous system (CNS) infection that can affect, for example, the brain or spinal cord. Crance does not disclose, teach or suggest that interferon alpha-2b could be used to treat infections in the CNS. Applicant directs the Examiner's attention to the previously submitted references, <http://www.cancercare.on.ca> and <http://www.vu-wien.ac.at/i123/allgemeininfo.html> (website visited February 17, 2003), and Smith *et al.* Clin Pharmacol Ther. 1985 Jan 37(1): 85-8 (abstract), discussing that interferon-alpha 2b has little or no penetration across the blood-brain barrier into the CNS. Thus, one of ordinary skill in the art would not expect interferon alpha-2b to be useful in treating a CNS infection associated with the West Nile virus. Applicant respectfully directs the Examiner's attention to Marfin and Gubler, West Nile Encephalitis: An Emerging Disease in the United States, *Clinical Infectious Diseases*, 33:1713-9 (2001), published after the filing of this application,

Applicant: Rahal, James
U.S. Serial No.: 09/935,966
Response to Non-Compliant Amendment
Page 7

where experts in the field describe that there is no effective therapy for treatment of West Nile virus (*see* Marfin at page 1717). Thus, before the presently claimed invention, one of ordinary skill in the art would not have any expectation of success in preventing or treating West Nile by administering interferon alpha-2b, because experts concluded that there was no effective treatment for West Nile virus infections.

Albrecht is cited by the Examiner for teaching that interferon alpha-2b can be used at doses of 3 to 10 million IU for the treatment of chronic hepatitis C viral infections—in the same family as the West Nile virus. However, Applicant respectfully submits that hepatitis C infections are localized viral infections of the liver that can result in cirrhosis of the liver, decompensated liver disease and/or hepatocellular carcinoma (*see* Albrecht col. 1, lines 4-8). These liver diseases are not the same as CNS infections involving the brain and/or spinal cord. As stated above, interferon alpha-2b does not penetrate the CNS to any great extent, interferon alpha-2b levels in the CNS are low, thus the *in vitro* data of Crance and the dosing regimen disclosed in Albrecht can not simply be applied to CNS infections such as meningitis, encephalitis, or meningo-encephalitis caused by the West Nile virus, because the site of the infection is different, and the penetration of interferon alpha-2b in the CNS is low. Accordingly, upon reading Crance and Albrecht alone or in combination, one of ordinary skill in the art would not obtain the present invention as claimed, nor would it be obvious to one of ordinary skill in the art. Even if one of ordinary skill in the art were to combine Crance and Albrecht, one may expect success at treating liver infections, not CNS infection. Accordingly, Applicants respectfully submit that the rejection under 35 U.S.C. §103(a) is improper, and Applicant requests withdrawal of this rejection.

Applicant: Rahal, James
U.S. Serial No.: 09/935,966
Response to Non-Compliant Amendment
Page 8

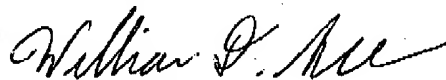
Conclusion

In view of the foregoing amendments, and the remarks set forth above, reconsideration and allowance are respectfully solicited.

No fee is believed to be due with respect to the filing of this response. If any additional fees are due, or an overpayment has been made, please charge, or credit, our Deposit Account No. 11-0171 for such sum.

If the Examiner has any questions regarding the present application, the Examiner is cordially invited to contact Applicant's attorney at the telephone number provided below.

Respectfully submitted,



William D. Schmidt
Registration No.: 39,492
Attorney for Applicants

Kalow & Springut LLP
Telephone: (212) 813-1600
Facsimile: (212) 813-9600